Individual Safety Report

3754442-8-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

'OLUNTARY reporting by health professionals of adverse events and product problems

Internet Submission - Page 1 of 2

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Form Approved: OMB No. 0910-0291 Expires: 04/2003
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 146773

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
982623	1 Years or Date of birth:	☐ female ☑ male	lbs or 10.2 kgs
In confidence			

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death (mm/dd/yyyy)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event: 07/03/2001 (mm/dd/yyyy)

4. Date of this report: 07/06/2001 (mm/dd/yyyy)

5. Describe event or problem

Child brought to the ER on 7/3 with a fever. Mom told RN she had given child 0.8ml of tylenol. RN told mom she had "way underdosed" the child and that he should get 5ml. RN demonstrated how to give 5ml tylenol in a syringe. The tylenol was red which is the same color of the drops they were using at home. Patient discharged with verbal instructions for 5ml of tylenol q4h x 6 doses. Written instructions said 150mg, but all of this transpired at 0200 when the parents were worried and weary. Parents gave 6 doses of 5ml tylenol DROPS to baby. Mom reports that it was difficult to pour the liquid out of the dropper bottle. They called the PCP because he was throwing up and febrile. The PCP discovered the discrepancy of the tylenol dose and referred the child to the children's hospital for follow-up. Child was admitted to [redacted] hospital on 7/5/01 for iv

6. Relevant tests/laboratory data, including dates

7/5/01 AST 134, ALT 109, PT 12.8, INR 1.1, APTT 57.2, ACETAMINOPHEN 7. 7/6/01 AST 131, ALT 103, PT 14.5, INR 1.5, APTT 73, AMMONIA 48.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

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C. Suspect medication(s)

1. Name (Product Name)	(Labeled Strength)	(Mfr/Labeler)
#1 TYLENOL INFANT DROPS	100MG/ML	MCNEIL
#2		

2. Dose/Frequency/Route used: #1 / #2

3. Therapy dates (if unknown, give duration): From / To (or best estimate)

4. Diagnosis for use (separate indications with commas): #1 / #2

5. Event abated after use stopped or dose reduced: #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known): #1 / #2

7. Exp. date (if known): #1 / #2

8. Event reappeared after reintroduction: #1 ☐ yes ☐ no ☐ doesn't apply; #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only): – –

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address: DRUG MALADMINISTRATION (Include Narrative)

4. Operator of device: ☐ health professional ☐ lay user/patient ☐ other:

5. Expiration date (mm/dd/yyyy)

6. model # / catalog # / serial # / lot # / other #

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7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA) ☐ yes ☐ no ☐ returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

1. Name: [redacted] phone # [redacted]

[redacted] Road

[redacted] United States

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to: ☐ manufacturer ☐ user facility ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 146773

Individual Safety Report

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For VOLUNTARY reporting by health professionals of adverse events and product problems

B5. Describe event or problem continued

N-acetylcysteine therapy.

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Mail to: MEDWATCH
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Rockville, MD 20852-9787

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